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ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
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September 27, 2018

The Honorable Scott Gottlieb, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
57 New Hampshire Ave,
Silver Spring, MD 20993

Dear Dr. Gottlieb:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee is examining concerns related to the Food and Drug Administration's (FDA) Office of Laboratory Science and Safety (OLSS).

In 2016, the FDA, in response to the discovery of vials containing smallpox and other highly infectious pathogens in an FDA-occupied cold room, established the OLSS to ensure that incidents of this nature do not happen in the future, and to centralize all laboratory science and safety activities under one office for oversight, reporting directly to the FDA commissioner. FDA also realigned the Employee Safety and Environmental Management Office under the OLSS to consolidate all safety functions under a single office for efficiency. In 2017, you as FDA commissioner submitted a reorganization package to HHS Secretary Tom Price that designated the head of the OLSS as a direct report to the FDA Commissioner. HHS approved the function of OLSS and the realignment in July 2017, and it was officially published in the July 25, 2017 Federal Register for public notification. This reorganization was consistent with the organizational structure at the Centers for Disease Control and Prevention, and with the recommendation of the HHS External Laboratory Safety Working Group (ELSW).

On June 15, 2018, the Subcommittee on Oversight and Investigations held a hearing on bio-preparedness. The FDA Chief Scientist testified at that hearing, including about the FDA OLSS. During the hearing, the FDA Chief Scientist acknowledged that, although the FDA has about 2,800 laboratory spaces, the OLSS had not conducted any inspections of these spaces over the last year. Further, the Chief Scientist testified that OLSS had only three permanent staff, not the 13 FTEs that the FDA had committed for OLSS in a September 2016 letter to the Committee.

The FDA Chief Scientist also testified that OLSS had reverted to directly reporting to the Chief Scientist rather than the Commissioner as provided in the July 2017 Federal Register notice.

To assist our oversight in this area, please provide the following by October 15, 2018:

1. Please provide a list of all safety incidents at FDA laboratories since January 1, 2016 including the following information: the date of the incident; description of the incident; description of any injury, infection or potential exposure; and information on potential exposure to biological, chemical, radiological or all other hazardous agents. If there was a laboratory-acquired infection or exposure, please name the agent involved, and what remedial action was taken to prevent such incidents from happening in the future. If there was an animal bite involved, please identify the animal, whether the animal had an infection, and what agent the animal was infected with. Please provide copies of any laboratory safety incident reports related to laboratory-acquired infections or exposure to biological, chemical, radiological or all hazardous agents, or reports related to an animal bite.

2. Please provide a list of all FDA buildings that contain a laboratory or animal facility, and their locations.

3. Have any FDA labs been inspected by the Federal Select Agent Program since January 1, 2016? Which labs? What were the findings? What corrective actions were recommended? Please provide copies of any inspection reports and their attachments.

4. Please provide copies of reports related to the reasons and justification as to why OLSS is being realigned again to report to the Office of the Chief Scientist. When was the decision made to have OLSS report to the Chief Scientist? When was the OLSS realignment to the Chief Scientist submitted to HHS? When did the Director of OLSS start reporting to the Chief Scientist?

5. In a recent meeting with FDA before the June 15 hearing, Committee staff were notified that OLSS staff included two Senior Executive Service officials (SES), two individuals on detail and one GS-13 employee. Why does OLSS require two SES officials to manage such a small team?

6. Are any other changes being made to the OLSS functions, activities, or responsibilities delineated in the July 25, 2017 Federal Register notice? If so, what changes are being made in terms of OLSS and its functions, activities, or responsibilities?

7. At the June 15th hearing, the Chief Scientist testified that as soon as there is a dedicated budget, the number of OLSS permanent staff will double to six, with a doubling of the number of staff the following year. When will OLSS have a dedicated budget? Please detail information for each of the proposed additional positions, including the title and grade level of the position, description of job duties and responsibilities, and proposed date of hiring.

An attachment to this letter provides additional information about complying with the Committee's request. If you have any questions regarding this letter, please contact Alan Slobodin with the Majority Committee staff at (202) 225-2927 or Kevin McAloon of the Minority staff at (202) 225-3641. Thank you for your prompt attention to this request.

Sincerely,

Greg Walden
Chairman

Frank Pallone
Ranking Member

Gregg Harper
Chairman
Subcommittee on Oversight
and Investigations

Diana DeGette
Ranking Member
Subcommittee on Oversight
and Investigations

Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

Gene Green
Ranking Member
Subcommittee on Health

Attachment